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10/581,040	04/12/2007	Grazyna Hansen	2003045-US2	4566
69289	7590	02/09/2010	EXAMINER	
COLOPLAST A/S			ASHBY, TANIA L	
Attention: Corporate Patents				
Holtedam 1			ART UNIT	
DK-3050 Humleback,			PAPER NUMBER	
DENMARK			1611	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/581,040	Applicant(s) HANSEN ET AL.	
	Examiner TANIA ASHBY	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>December 18, 2006 and August 5, 2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

Instant claims 1-14 are pending and are the subject of this office action.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on December 18, 2006 was noted and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the information disclosure statement. References JP 10 33655 and JP 6 199660 have been lined through because they are considered duplicative in light of the full translation of these documents provided on the subsequent IDS dated August 5, 2008.

The information disclosure statement (IDS) submitted on August 5, 2008 was noted and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the information disclosure statement.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP402270818A ('818, published November 5, 1990,English translation attached) in view of JP 06199660 A ('660, published July 19, 1994, cited on Applicant's IDS).The '818 reference teaches a patch comprising a polyurethane film (title) of 4-150 micrometers thickness and also a tacky agent layer (i.e., adhesive layer) having a thickness of 30 to 2000 micrometers and a water vapor transmission (i.e. vapor permeability) of 300-500 g/m² (page 2).

The '818 reference does not appear to explicitly teach hydrocolloid particles in the adhesive layer nor does the '818 reference appear to explicitly teach a patch having a substantially uniform thickness.

The '660 reference teaches a patch with good drug release properties (title) comprising an adhesive layer containing cellulose particles having a size ranging from 1-150 micrometers (abstract). The '660 reference also teaches a support which may comprise a polyurethane film (paragraph [0035], page 9) The '660 reference further teaches an example of a mixture and a non-woven cloth having a defined, uniform thickness of 150 microns and 30 microns being applied to a polyethylene coating paper (paragraph [0054], pages 14-15).

It would have been prima facie obvious to one having ordinary skill in the art at the time of the invention to combine the teachings of the '818 reference with the hydrocolloid cellulose particles and uniform thickness taught by the '660 reference. One would have been motivated to do so because the '660 reference teaches that the patches of the invention have low skin irritability and good release properties for active agents (page 1, see "object" paragraph).

Regarding claims 1 and 3-5, the '818 reference teaches a patch for application to the skin (page 4, paragraph 1) comprising a backing layer made up of a polyurethane film (page 4, paragraph 2), a tacky agent layer (i.e. adhesive layer) having a thickness ranging from 30 to 2000 micrometers and a water vapor transmission (i.e. vapor permeability) of 300-500 g/m² (page 2). The '660 reference teaches plasters comprising an adhesive layer containing cellulose particles having a particle size ranging from 1-

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150 micrometer thickness (abstract). MPEP 2144.05 states that where the prior art ranges overlap or encompass the instantly claimed ranges, a prima facie case of obviousness exists.

In regards to the statement “being able to adhere to the skin or mucosa, and/or a wound,” the '818 reference teaches that the patch has excellent applying properties (page 4, paragraph 1) and the '660 reference teaches an adhesive layer and that the patch has low skin irritability (page 1, see “Object” and “Constitution”) and would therefore be able to adhere to the skin.

In regards to the statement “for covering a portion of the anatomical surface of a living being,” such a statement is merely intended use and does not limit claim scope unless it affords a structural difference to the claimed product. In the instant case, it does not result in a structural difference and therefore is not limiting. However, also note that both references teach patches for applications to the skin.

In regards to the vapor permeability and the absorption of the patch, given that the prima facie obvious combination of the prior art yields a composition that is essentially identical to that Applicant is claiming, the prior art product would necessarily possess the claimed properties. Also see *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977), “where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established,” and *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990), “when the PTO shows a sound basis for believing that the

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products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.”

In the instant case, the combination of the prior art yields a patch identical in composition (having a backing layer and an adhesive layer of hydrocolloid particles) and structure (the adhesive layer being of the required thickness) and therefore the burden is properly shifted to Applicant to present evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product.

Also note that on page 5, paragraph 3 of the instant disclosure, Applicant relates the amount of absorption to the thickness of the adhesive layer stating, "The idea is the thicker dressing, the more hydrocolloid particles and the higher absorption." Given that the thickness of the adhesive layer taught by the prior art overlaps and thus renders prima facie obvious the thickness of the adhesive layer claimed by Applicant, and Applicant alludes to absorption being a function of increasing thickness, the skilled artisan would reasonably expect that the absorption of the patch taught by the prior art, if able to be measured, would meet the instantly claimed limitation.

Regarding claim 2, page 2 of the '660 reference teaches an example of a mixture and a non-woven cloth having a defined, uniform thickness of 150 microns and 30 microns being applied to a polyethylene coating paper (paragraph [0054], pages 14-15). Although the reference does not explicitly state that the patch is of a uniform thickness, MPEP 2144.01 states that “in considering the disclosure of a reference, it is proper to take into account not only specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom.” Also see

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In re Preda, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968). In the instant case, the example taught by the prior art shows that two components having a single defined thickness (i.e. 30 microns and 150 microns) are applied to a coating paper. The skilled artisan would assume that given that the thickness of the components being applied does not vary, the thickness of the overall patch would also not be substantially variable.

Regarding claims 6-7, the cellulose hydrocolloid particles of the '660 reference have a size ranging from 1-150 microns (page 1, see "Constitution" paragraph), overlapping and thus making prima facie obvious the claimed ranges of "less than 125 micrometers" and "less than 50 micrometers."

Regarding claim 8, given that the prima facie obvious combination of the prior art yields a composition that is essentially identical to that Applicant is claiming, the prior art product would necessarily possess the claimed reflectance. Also see *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977), "where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established," and *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990), "when the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not."

In the instant case, the combination of the prior art yields a patch identical in composition (having a backing layer and an adhesive layer of hydrocolloid particles) and

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structure (the adhesive layer being of the required thickness) and therefore the burden is properly shifted to Applicant to present evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product.

Regarding claims 9-10, the backing layer of the '880 reference is a polyurethane film having a thickness of 4-150 micrometers (page 2, paragraph 2). Such a range overlaps and thus renders prima facie obvious the claimed thickness range.

Regarding claim 11, the '660 reference teaches that the adhesive layer is applied to the polyethylene coating paper in a uniform manner and thus is uninterrupted.

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP402270818A ('818, published November 5, 1990, Derwent abstract only) in view of JP 06199660 A ('660, published July 19, 1994, cited on Applicant's IDS), as applied to claims 1-10 above, and further in view of Hirsch (U.S. 3,658,065, issued April 25, 1972).

The rejection of claims 1-11 has been discussed supra.

The '818 reference teaches a patch comprising a polyurethane film (title) of 4-150 micrometers thickness and also a tacky agent layer (i.e., adhesive layer) having a thickness of 30 to 2000 micrometers and a water vapor transmission (i.e. vapor permeability) of 300-500 g/m² (page 1).

The '660 reference teaches a patch with good drug release properties (title) comprising an adhesive layer containing cellulose particles having a size ranging from 1-150 micrometers (page 1, see "Constitution" paragraph). The '660 reference further

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teaches an example of a mixture and a non-woven cloth having a defined, uniform thickness of 150 microns and 30 microns being applied to a polyethylene coating paper (page 2, paragraph 4).

Neither reference appears to explicitly teach a patch having an absorbent pad or one or more cavities.

The Hirsch reference is drawn to an absorbent bandage with an integral reservoir for the storage of fluids (abstract).

It would have been prima facie obvious to one having ordinary skill in the art at the time of the invention to combine the teachings of the '818 and '660 references with the absorbent pad and reservoir taught by Hirsch. One would have been motivated to do so because Hirsch teaches that an absorbent pad and reservoir is advantageous because it eliminates the need for frequent replacement of the patch (because the patch is absorbing any wound exudate or sweat from the skin) and further decreases discomfort of the patient. See column 1, lines 6-19.

Regarding claims 12-13, the absorbent pad and the reservoir are taught in column 1, lines 1-5 and also in column 2, lines 42-61.

Conclusion

No claims are currently allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TANIA ASHBY whose telephone number is (571)270-1348. The examiner can normally be reached on Monday through Friday, 7:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/TA/

/David J Blanchard/
Primary Examiner, Art Unit 1643